February 17, 2022

TO: Marin Healthcare Providers

RE: COVID-19 Therapeutics

Background

The Food and Drug Administration (FDA) has authorized emergency use of oral antiviral medications for COVID-19. Due to the extremely limited supply of these medications during initial release, Marin County Public Health has convened a Multi-Agency Coordination (MAC) group to review and approve scarce resource criteria and allocations.

Guidance

Current EUA-approved antivirals have significant contraindications, warnings and precautions, adverse reactions, and drug interactions. Providers should carefully review the full EUA fact sheets before prescribing. These experimental therapies are rarely indicated for the general population with an active COVID-19 infection.

There is an extremely limited supply of antivirals allocated to Marin County. Pharmacies / providers may not have supply to fill prescriptions when ordered. Healthcare providers can only prescribe antiviral medications to patients who meet eligibility criteria approved by Marin County MAC Therapeutics Group.

1. Prescribing providers must confirm:
   a. Patient is a resident of Marin County; and,
   b. Patient must have an active COVID-19 infection confirmed by a positive rapid antigen or molecular test after testing for symptoms or for known exposure to a probable or confirmed case.
   c. Patient should be provided treatment within 3 – 5 days of symptom onset; and,
   d. Patient meets eligibility as determined by the FDA EUA:
      i. Paxlovid: FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR PAXLOVID (fda.gov), or
      ii. Molnupiravir: FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR MOLNUPIRAVIR (fda.gov)
   e. Provider must review contraindications, warnings and precautions, adverse reactions, and drug interactions with patients;
      i. Notably, Ritonavir-boosted nirmatrelvir (Paxlovid) has significant and complex drug-drug interaction potential. Clinicians who are not experienced in prescribing ritonavir-boosted drugs should refer to the Liverpool COVID-19 Drug Interactions website for additional guidance. Consultation with an expert (e.g., clinical pharmacist) should also be considered.
Patient must be in one of the following treatment categories:

i. Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status. See list below for Immunocompromising Conditions and Treatments

ii. Unvaccinated or unboosted individuals at the highest risk of severe disease.

iii. Age ≥65 years.

iv. Age <65 years with at least one CDC-defined Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19. See list below.

2. For Kaiser Permanente providers, if potential candidates for oral Paxlovid or IV Sotrovimab are identified, contact “Covid MAb” consultant found on Clinconnect/OnCall to discuss logistics.

3. Non-KP providers:

Providers who have patients with mild to moderate COVID-19 that do not require emergency room evaluation and meet criteria for treatment with Paxlovid or Monulpravir should submit prescriptions to Golden Gate Pharmacy or Rite Aid. Patients who require emergency care due to severity of symptoms should be referred to the emergency room for evaluation.

a. Golden Gate Pharmacy – Delivery will not be made until the pharmacy has received the E-script; completed online form; and notified the patient.

i. Hours: Monday thru Friday 9 – 5 pm (Orders received over the weekend will be processed on Monday)

ii. Delivery Only - Patients should NOT pick up from the pharmacy (no charge for delivery). Deliveries will be made in North, South, and Central Marin, and as far west as Fairfax.

iii. Providers only can complete online form to attest for the prescription (code: MAC2022)

b. Rite Aid Northgate Pharmacy, 1500 Northgate Mall, San Rafael, CA 94903.

i. Providers can call the pharmacy to submit a prescription: (415) 492-0888.

ii. Providers should instruct patients that they need to pick up medication and start regimen within 24 hours.

Immunocompromising Conditions and Treatments List

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell therapy or hematopoietic cell transplant (HCT) Within 2 years of transplantation OR on immunosuppressive therapy
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection:
- HIV and CD4 cell counts <200/mm3
- History of an AIDS-defining illness without immune reconstitution
- Clinical manifestations of symptomatic HIV
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day for ≥ 2 weeks); alkylating agents; antimetabolites;
transplant-related immunosuppressive drugs; cancer chemotherapeutic agents classified as severely immunosuppressive; tumor necrosis factor (TNF) blockers; or other biologic agents that are immunosuppressive or immunomodulatory

CDC-defined Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19

- Cancer
- Cerebrovascular disease
- Chronic kidney disease
- Interstitial lung disease
- Current pulmonary embolism
- Pulmonary hypertension
- Bronchopulmonary dysplasia
- Bronchiectasis
- COPD
- Cirrhosis
- Non-alcoholic fatty liver disease
- Alcoholic liver disease
- Autoimmune hepatitis
- Diabetes mellitus, type 1 and type 2
- Congestive heart failure
- Coronary artery disease
- Cardiomyopathy
- Mood disorders - including depression, Schizophrenia spectrum disorders
- Obesity (BMI >= 30 kg/m2)
- Pregnancy
- Smoking
- Active Tuberculosis
- Social determinants of health, which may include but are not limited to: unstable housing, poverty or food insecurity, single head of household in minimum wage employment, non-English speaking immigrant, active substance use disorder.